UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/425,289	10/25/99	TONER	J REF/TONER/19

HM22/1102

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EXAMINER	
HARTLEY, M	
ART UNIT	**PAPER NUMBER**
1619	

DATE MAILED: 11/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/425,289	Toner et al.
Examiner	**Group Art Unit**
Michael G. Hartley	1619

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-37* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-37* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method of embolus therapy comprising administering particles and detecting the localization thereof by a diagnostic imaging technique, classified in class 424, subclass 9.4+.

II. Claims 8-18, drawn to a method of radiation therapy, classified in class 424, subclass 1.29.

III. Claims 19-34, drawn to a method of chemoembolic therapy comprising administering particles containing a therapeutic agent which is a promoter of vascular growth, classified in class 424, subclass 489.

IV. Claim 35, drawn to a method of identifying local pharmacokinetics in tissue, classified in class 424, subclass 9.1.

V. Claim 37, drawn to a pharmaceutical composition comprising contrast-effective particles together with a physiological tolerable sterile liquid, classified in class 424, subclass 9.3+.

Note: Claim 36 has not been included in any of the above Grouped inventions, since this claim is drawn to a non-statutory invention (e.g., this claim is a non-statutory "use" claim). Also, while claim 12 depends on claim 1, this claim has been grouped in Group II, since the dependency on claim 1 appears to be a typographical error and this claim should be dependent on claim 8 (e.g., this is apparent since claim 1 does not include radiation, as set forth in claim 12).

The inventions are distinct, each from the other because of the following reasons: Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together because they have different modes of operation, effects and functions. For example, Group requires an iodinated X-ray contrast agent, MR agent or ultrasound agent and a method of detecting thereof, while Group II requires radiation therapy. Group III requires a chemotherapeutic agent which is a promoter of vascular growth, while Group IV requires identifying local pharmacokinetics in tissue.

Inventions V and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product may be used in various methods of chemotherapy, embolic therapy, MRI, X-ray imaging, ultrasound imaging, etc.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: 1) various particle forming materials, e.g., a matrix material, non-radioactive diagnostic effective material, etc., including, metal oxides, insoluble metal salts, inert metals, glass, ceramic particles, etc, 2) various contrast agents (if present in the elected group) and 3), various therapeutic agents (if present in the elected group).

Applicant is required under 35 U.S.C. 121 to elect a **single disclosed species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8, 19, 35 and 37 are generic.

Note: A single disclosed species will name a specific compound for each of the components which are present in the composition set forth the elected group.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations

of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center Custom Service Center whose telephone number is (703) 308-1235. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Michael Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on Tuesdays through Fridays and on alternate Mondays from 7:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703) 308-2328. The fax phone number for this Group is (703) 308-4556.

Date: 10/31/2000

Michael G. Hartley
Patent Examiner
Art Unit 1619